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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,139	05/19/2006	Leon Rudakov	077567-0021	9222

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EXAMINER	
DORNBUSCH, DIANNE	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
09/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,139	RUDAKOV ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-22,24-36,39 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-22,24-36,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
>
> It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 34 mention a uniform porosity, but the original disclosure describes a range of pores that can be used on the membrane and the figures only show a portion of the pores.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 34 disclose that the pores are uniform, that the blood cannot pass to the aneurysm through the membrane, and that blood can pass through the membrane into branch vessels.

It is unclear to the examiner how blood cannot pass through a portion, but can pass through another portion of the membrane if the pores are uniform.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-13, 15-20, 24-31, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al (6,451,050) in view of Fierens et al. (2002/0035394).

Claim 1:

Rudakov discloses a medical device (11) for insertion into a bodily vessel, the device comprising: a mechanically expandable device (16) expandable from a first position to a second position (Col. 5 Lines 15-17), such that in the second position, an exterior surface of said mechanically expandable device engages with the inner surface

of the vessel so as to maintain a fluid pathway through said vessel (Col. 5 Lines 13-17). The mechanically expandable device (16) is engaging through the vessel by expanding radially and providing the rigidity on the top sleeve (13) in order to maintain contact with the vessel.

Furthermore Rudakov discloses that a porous membrane expandable (12, 13) (Col. 2 Line 16) in response to expansion of the mechanically expandable device (16) (Col. 5 Lines 15-17); wherein at least a portion of the membrane is secured to the mechanically expandable (the membrane is attached to the mechanically expandable device by using rings 17 and by everting the membrane in order to hold the mechanical expandable device as disclosed in the Col. 3 Lines 48-65), such that a proximal end of the membrane is proximate to a proximal end of the mechanically expandable device, and a distal end of the membrane is proximate to a distal end of the mechanically expandable device (Col. 3 Lines 48-65); and wherein the membrane has a porosity over a length extending from the distal end of the membrane to the proximal end of the membrane (the membrane is made of a material which contains pores throughout the material in order to optimize desired biological responses; wherein when the mechanically expandable device is expanded in the bodily vessel, adjacent to the aneurysm, the membrane is effective to: obstruct blood flow from the vessel into the aneurysm (the device can be placed in a vessel to treat an aneurysm by placing it between the opening where part of the device is covering the aneurysm thereby obstructing the flow by using the porous membrane); and permit blood flow through pores in the membrane and into branch vessels arising from the bodily vessel.

With respect to the statements of what the membrane is effective to do (capable of), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Additionally, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Rudakov teaches all the claimed limitations discussed above however, Rudakov does not disclose that the membrane has a substantially uniform porosity.

Fierens discloses a mechanically expandable device (32) with a membrane (38) that contains a substantially uniform porosity (last sentence of [0024] and [0087]) along its length (Fig. 11 and [0087] last line).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov with a uniform porosity in view of the teachings of Fierens, in order to promote cell in growth as well as reducing the risk of embolic release through out the length of the device equally.

Claims 2 and 18: Rudakov in view of Fierens discloses the claimed invention except for distance between adjacent pores being between 40 to 100 microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the distance between adjacent pores between 40 to 100 microns, since it has

been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 3: Rudakov discloses that the membrane (12, 13) is made of a biocompatible and elastomeric polymer (Col. 2 Lines 10-21).

Claim 4: Rudakov discloses that the membrane (12, 13) has a thickness of about 0.0005 to 0.005" (Col. 2 Lines 22-25).

Claim 5:

Rudakov discloses all the claimed limitations discussed above but it is silent in the distance between adjacent pores, therefore it is silent on the material surface area of the membrane being from about 25-75%.

Although Rudakov does disclose the range size for the pores, which indicates that the surface area of the membrane is less than 100%. By identifying the pore size and the spaces between each pore the surface area of the membrane can be identified.

As mentioned in the rejection of claim 2, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the distance between adjacent pores between 40 to 100 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a membrane with a surface area between 25 to 75%, since it has been held that where the general conditions of a claim

are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 6: Rudakov discloses that the membrane (12, 13) has pores between 20 to 100 microns in size (Col. 2 Lines 28-29).

Claim 7: Rudakov discloses that the membrane (12, 13) is made from polymeric material (Col. 2 Lines 10-13).

Claim 8: Rudakov discloses that the polymeric material forms multiple sub-layers mixed with drugs or reagents (Col. 3 Lines 26-29 and Col. 4 Lines 41-43 and Lines 58-61). The layers are formed by each of the coatings on the membrane.

Claim 9: Rudakov discloses that the membrane (12, 13) is capable of isotropic expansion (Col. 5 Lines 13-17).

Claim 10: Rudakov discloses that the membrane (13) is disposed on the exterior surface of the device (16) (Col. 2 Lines 4-5 and Fig. 1).

Claim 11: Rudakov discloses that the membrane (12, 13) completely surrounds the device (Col. 3 Lines 52-58). There is only one material use to form the outer membrane (13) and the inner membrane (12) which surrounds the device (16) as disclosed in the method of manufacturing in Col. 3 Lines 42-67.

Claim 12: Rudakov discloses that the membrane (12, 13) circumferentially surrounds a portion of the device (Fig. 2 and Col. 3 Lines 48-65).

Claim 13: Rudakov discloses that the membrane (12, 13) covers a portion of the device (Fig. 2).

Claim 15: Rudakov discloses a membrane is made from a solid polymer (Col. 2 Lines 10-13). The polymer is solid since it has three dimensions (length, breadth, and thickness) (Col. 2 Lines 22-25 and Fig. 1-4).

Claims 16 and 17:

Rudakov discloses each and every structural element of the membrane set forth in claims 16 and 17 (Col. 2 Lines 28-29).

Rudakov teaches that the membrane comprises pores between 20 to 100 microns in size (Col. 2 Lines 28-29), but is silent as to the method of making the pores. The claimed phrase “fabricated pores” and "fabricated by laser drilling" are being treated as a product by process limitation; that is, that the pores are made by laser drilling.

Fierens teaches that the membrane has fabricated pores ([0024]) and that the pores are fabricated by laser drilling ([0024]).

Therefore, even if “laser drilling” results in different structural characteristics of the end product than other pore fabricating methods, it still would have been *prima facie* obvious at the time the invention was made to use a “laser drilling fabrication method” in Rudakov as claimed since Fierens teaches that laser drilling is recognized as a useful technique for forming the pores in the membrane.

Claim 19: Rudakov discloses that the membrane (12, 13) comprises a plurality of polymeric strips (17) (Col. 2 Lines 55-58) secured to the mechanically expandable device (16) (Col. 2 Lines 5-6 and 63-64).

Claim 20: Rudakov in view of Fierens discloses the claimed invention except for the strips being less than 0.075 mm and a distance between adjacent strips being less than 100 um. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the size of the strips less than 0.075 mm and a distance between adjacent strips less than 100 um, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 24: Rudakov discloses that the mechanically expandable device (16) comprises a generally tubular structure (Fig. 1) having an exterior surface defined by a plurality of interconnected struts (26 with 22 and 23) having interstitial spaces therebetween (Fig. 1).

Claim 25: Rudakov discloses the mechanically expandable (16) device is balloon expandable (Col. 5 Lines 13-17).

Claim 26: Rudakov discloses that the mechanically expandable device (16) is a stent (Fig. 1). Figure 1 shows that the expandable device (16) has the structure of a stent as well as Rudakov discloses that the final product is a stent-graft where the expandable device (16) is the stent and the graft is the membrane (12, 13).

Claim 27: Rudakov discloses that the membrane (12, 13) is supported by the generally tubular structure (Fig. 1) and is attached to at least one strut (26) as seen in Fig. 1-3 as well as in the explanation of the manufacturing process (Col. 4Lines 1-14) where the membrane (12, 13) are placed on the expandable device (16).

Claim 28: That the membrane (12, 13) is tubular (Fig. 1-2) and wherein the membrane (30) is disposed onto the outer surface of the stent (Fig. 1-2).

Claim 29: That the membrane (12, 13) is a segment of a tubular structure (Fig. 1-2) disposed onto a portion of the outer surface of the stent (Fig. 1-2).

Claim 30: Rudakov discloses that the at least one drug or reagent is in any one form selected from the group consisting of: solid tablet, liquid and powder (Col. 4 Lines 36-49).

Claim 31: Rudakov discloses that at least one radiopaque marker is provided on the mechanically expandable device (16) to improve visibility of the device during and after insertion (Col. 4 Lines 17-21).

Claim 35 and 36: Rudakov discloses a method of manufacturing comprising: disposing the generally tubular structure on a mandrel (51); and disposing the membrane (12,13) onto the outer surface of the mechanically expandable device (16). The device has two membranes, where the first membrane (12) is first disposed on the mandrel (51) and then the expandable device/stent (16) is placed on the mandrel as well as the connecting rings (17). After this part the membrane (13) is placed on top of the mechanically expandable device/stent as it is disclosed in Fig. 3-4 and Col. 4 Lines 1-14.

8. Claims 2, 5, 18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al (6,451,050) in view of Fierens et al. (2002/0035394) and further in view of Solovay (5,769,884) .

Solovay discloses a medical device (10) for insertion into a bodily vessel, the device comprising: a mechanically expandable device (20) expandable from a first position to a second position (Col. 3 Line 44), said mechanically expandable device (20) is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel (16) so as to maintain a fluid pathway through said vessel (Col. 3 Lines 50-59). Figure 4 shows how the expandable device (20) is in contact with the vessel (16).

Furthermore it is disclosed that a membrane expandable (30) from a first position to a second position in response to expansion of said mechanically expandable device (20) (Fig. 3-4 where the device is expanded), said membrane (30) being positioned proximal to the aneurysm (15) and obstructing blood circulation to the aneurysm (15) when expanded to the second position (Fig. 3-4), and at least a portion of the membrane (30) is secured to the mechanically expandable device (20) to maintain the position of the membrane (30) relative to the mechanically expandable device (20) when expanded to the second position (Col. 3 Lines 45-50); wherein the membrane (30) is permeable (it can be penetrated, especially by liquids or gases, depending on the size of the pores, such as drug agents) and porous (Col. 3 Line 45-46), the size of the pores of the membrane and the ratio of the material surface area of the membrane being such that blood supply to perforators and/or microscopic branches of main brain arteries is permitted to improve healing of the bodily vessel but blood supply to the aneurysm is prevented (Col. 2 Lines 1-9).

Claims 2 and 18:

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that the distance between adjacent pores is from 40 to 100 microns.

Solovay discloses that the distance between adjacent pores is from about 40 to 100 microns (Col. 2 Lines 51-55 and Col. 5 Lines 51-53). The pore size is between 30-120 microns (Col. 2 Lines 34-35 and Col. 5 Lines 5-7) therefore the space between the pores is in the specified range. For example if the pore size is 30 microns than the space between the pores can be 90 microns.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with the specified distance range between adjacent pores in view of the teachings of Solovay, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 5:

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that the surface area of the membrane is from 25 to 75%.

Solovay discloses that the ratio of the material surface area of the membrane (30) is from about 25 to 75%. Do to the size of the pores and the space between the pores the surface area of the membrane is between that range. For example if the membrane has pores spaced close together like the one shown in Fig. 6 section 12 it

can be seen that if the pore size were 30 microns and the space between them were 15 microns the surface area would be around 30%-50%.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with the specified surface area range of the membrane in view of the teachings of Solovay, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 20:

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not discloses that the strips are less than 0.075 mm and a distance between adjacent strips is less than 100 um.

Solovay discloses that the membrane (30) comprises a plurality of polymeric strips (the fiber disclosed in Col. 7 Lines 15-16) secured to the mechanically expandable device (20) (Col. 7 Lines 45-48).Additionally, Solovay discloses that the strips (the fiber) are less than 0.075 mm (Col. 7 Lines 15-18) and the distance between adjacent strips (fibers) is less than 100 microns. There are strips that are grouped together which will have a distance of less than 100 microns, furthermore the strips are interlaced forming the pores which are around 30-120 microns. So the distance from one strip is less than 100 microns.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with the specified

distance range between adjacent strips and the size of the strips in view of the teachings of Solovay, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 21 and 22:

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not discloses that the membrane comprises a mesh.

Solovay discloses that the membrane comprises a mesh secured to the mechanically expandable device (20). The mesh is the membrane (30) which is braided which forms a mesh structure (Col. 3 Lines 45-48).

Additionally Solovay discloses that the spaces (the pores) of the mesh (30) are less than 100 microns (Col. 2 Lines 34-35 and Col. 5 Lines 5-7).

However, Solovay discloses the claimed invention except that the width of the meshing is between 0.025 to 0.050 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width of the meshing be between 0.025 to 0.050 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with a mesh membrane

in view of the teachings of Solovay, in order to fabricate the pores by spacing the area between each wire in the mesh to the desired pore size.

9. Claims 34, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume et al. (5,948,018) in view of Fierens et al. (2002/0035394).

Claim 34:

Dereume discloses a medical device for treating a bifurcation or trifurcation intracranial aneurysm between at least two bodily vessels, the device comprising: a first mechanically expandable device (57), expandable from a first position to a second position (Fig. 9-13), such that, in the second position, an exterior surface of the first mechanically expandable device engages with an inner surface of a first branch vessel arising from a parent vessel so as to maintain a fluid pathway through the first branch vessel (Fig. 13); a second mechanically expandable device (55, 56), expandable from a first position to a second position (Fig. 9-13), such that, in the second position, an exterior surface of the second mechanically expandable device engages with an inner surface of a second branch vessel arising from the parent vessel so as to maintain a fluid pathway through the second branch vessel (Fig. 13). The mechanically expandable devices are engaging through the vessel by expanding radially and providing the rigidity on the top membrane in order to maintain contact with the vessel.

Furthermore Dereume discloses a porous membrane (53, 54) (Claim 1 and 18) , and at least a portion of a proximate end of the membrane is secured to the first mechanically expandable device and a distal end of the membrane is secured to the second mechanically expandable device (Fig. 10); the membrane has a porosity over a

length extending from a distal end of the membrane to a proximal end of the membrane (Fig. 10); and wherein, when the first mechanically expandable device is expanded in the first branch vessel adjacent to the aneurysm and the second mechanically expandable device is expanded in the second branch vessel adjacent to the aneurysm position (the device can be placed in a vessel to treat an aneurysm by placing it between the opening where part of the device is covering the aneurysm thereby obstructing the flow by using the porous membrane), the membrane is effective to at least partially obstruct blood flow into the aneurysm; and permit blood flow through pores in the membrane and into that blood supply to perforators and/or microscopic branches of brain arteries.

With respect to the statements of what the membrane is effective to do (capable of), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Additionally, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Dereume teaches all the claimed limitations discussed above however, Dereume does not disclose that the membrane has a substantially uniform porosity.

Fierens discloses a mechanically expandable device (32) with a membrane (38) that contains a substantially uniform porosity (last sentence of [0024] and [0087]) along its length (Fig. 11 and [0087] last line).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dereume with a uniform porosity in view of the teachings of Fierens, in order to promote cell in growth as well as reducing the risk of embolic release through out the length of the device equally.

Claim 39: Dereume discloses that the membrane expands in response to expansion of the first mechanically expandable device (Fig. 9-13).

Claim 40: Dereume discloses the method wherein the membrane expands in response to expansion of the first and second mechanically expandable devices (Fig. 9-13).

10. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al (6,451,050) in view of Fierens et al. (2002/0035394) and further in view of Dereume et al. (5,639,278).

Claim 32:

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that at least one radiopaque marker is made from gold or platinum.

Dereume discloses that at least one radiopaque marker is made from gold or platinum (Col. 14 Lines 44-46).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with a radiopaque

marker made of gold or platinum in view of the teachings of Dereume, since this materials are well known in the art to be used as radiopaque markers.

Claim 33:

Rudakov discloses that there is a radiopaque marker at the end of the expandable device (Col. 4 Lines 17-19).

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that there is radiopaque marker at the center of the expandable device.

Dereume discloses that there is radiopaque marker at the center of the expandable device (Col. 14 Lines 38-44). The radiopaque marker is placed in the bifurcation area which is at the center of the mechanical expandable device.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with a radiopaque marker at the center of the device in view of the teachings of Dereume, in order to provide visualization of the graft and specifically of the area where the bifurcation or aneurysm is located.

Response to Arguments

11. Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773